



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,118	09/24/2003	Salim Yusuf	77101-002002	2545
69713 7590 12/29/2008 OCCHIUTI ROHLICEK & TSAO, LLP 10 FAWCETT STREET CAMBRIDGE, MA 02138				
EXAMINER				
NGUYEN, BAO THUY L				
ART UNIT		PAPER NUMBER		
1641				
NOTIFICATION DATE		DELIVERY MODE		
12/29/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary

Application No.

10/670,118

Applicant(s)

YUSUF ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20, 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The response dated 15 September 2008 has been received.
2. Claim 21 have been canceled. Claims 16-20 and 22-25 are pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16, 17 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Clemmons (US 5,030,555) for reasons of record which are reiterated herein below.

Claim 16 is limited to a kit comprising a first strip having labeled antibody thereon and a second strip for absorbing test sample. The intended use of the strips is not given patentable weight. If the prior art structure is capable of performing the intended use, then it meets the claim.

Clemmons discloses a "dip-stick" type device on which is located a plurality of test pads (102a-d). Each test pad is secured to a backing strip (104). Each test pad includes a porous membrane 106 (i.e. second strip) attached to the support member around the periphery thereof. A matrix (108) is positioned between the membrane and the support member. The test pads have antibodies absorbed thereon on the side of the membrane adjacent to the matrix, while the matrix contains labeled antibody (i.e. first strip having antibody bound to a reporter molecule).

See column 8, lines 10-68. In use, sample fluid enters through the membrane 106 and into the matrix 108. Analytes in the sample is captured by the antibody bound to membrane 106. Fluid entering matrix 108 mobilizes the labeled antibody 112 to form a labeled immunoreagent-analyte-antibody sandwich bound to the membrane 106. See column 9, lines 1-41.

With respect to claim 17, Clemmons discloses at least four test pads containing predetermined amount of labeled reagent to detect analytes. See example 4.

With respect to claim 19, Clemmons discloses the use of enzyme labels. See column 7, lines 16-21.

Even though Clemmons does not specifically teach a kit comprising the test strips, the kit of the instant invention is nothing more than the test strips themselves, and since Clemmons anticipates the test strips, Clemmons is seen to disclose the invention as claimed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 20, 22-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemmons in view of Reinke et al (IDS – AT)

Clemmons differs from the instant invention in failing to teach that the device can detect thromboxane B2.

Reinke, however, discloses the importance of detecting thromboxane B2 and teaches assays for their detection. Reinke discloses thromboxane B2-BSA conjugates, monoclonal antibodies specific to thromboxane B2 and three different types of enzymes detection system.

Even though the instant claims are not limited to reagents specific for thromboxane B2, the device of kit can be adapted carry reagents specific for the recited analyte. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Clemmons to detect thromboxane B2 using the reagents taught by Reinke because Clemmons teaches that their device is suitable for a variety of analytes with the choice of appropriate reagents. A skilled artisan would have had a reasonable expectation of success in using the device taught by Clemmons to detect thromboxane B2 because Reinke teaches that the measurement of thromboxane is important because an increase in biosynthesis of thromboxane is observed in patients with coronary diseases as well as a hosts of other problems, and Clemmons teaches that their device is unique in that it can be readily and easily used or performed by minimally trained personnel.

7. Claims 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemmons in view of Reinke as applied to claim 16 above, and further in view of Guire (US 4,826,759).

Clemmons and Reinke are discussed above. These references differ from the instant invention in failing to teach the use of dyes as labels.

Guire discloses both enzymes and leuco dyes as labels in an immunoassay. See column 13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the enzyme label taught by Clemmons and Reinke with the leuco dyes taught by Guire because they are functionally equivalent.

Response to Arguments

8. Applicant's arguments filed 15 September 2008 have been fully considered but they are not persuasive.

Applicant argues that Clemmons differs from the instant claims in failing to teach to strips.

This argument is not persuasive. The instant claims do not require that the first and second strip be separate strips, only that the first strip has a test patch containing a predetermined amount of labeled antibody specifically to the analyte and a second strip for absorbing a sample.

Strips comprising the same reagent and having the same functions are taught by Clemmons. The membrane 106 of Clemmons is seen to be equivalent to the second strip of the instant claim. This membrane is designed to receive a sample of analyte. The matrix 108 is seen to be equivalent to the first strip of the instant claim. It is a test patch comprising a labeled binding partner for the analyte. In use, sample fluid enters through the membrane 106 (second strip) and into the matrix 108 (first strip). Analytes in the sample is captured by the antibody bound to membrane 106. Fluid entering matrix 108 mobilizes the labeled antibody 112 to form a labeled immunoreagent-analyte-antibody sandwich bound to the membrane 106. See column 9, lines 1-41. The open transition "comprising" phrase in the claim does not require the two strips to be separate strips nor prevent or limit them from being configured together. Figures 12-15

show the membranes 106 and 108 as being two different entities, thus Clemmons anticipates or in the alternative makes obvious the instant claims.

The argument that the antibody matrix of Clemmons contains two antibodies specific to an analyte which differs from the instant test patch which includes only one antibody specific to an analyte is not persuasive. The transitional term comprising and including is inclusive or open-ended and does not exclude additional elements.

The argument that the additional antibody recited by Clemmons would compete with the labeled antibody for binding to the analyte defeating the intended use of the kit is not persuasive. The second antibody recited by Clemmons in no way competes for binding to the analyte. As can clearly be seen from Figures 12-15 and through the description, this additional antibody participates in a sandwich assay between the analyte and the labeled antibody. Unless the two antibodies taught by Clemmons bind to the same epitope on the analyte, they do not compete with each other to bind to the analyte. Clearly, in the event that no analyte is present in the sample, the labeled antibody remains on the first strip and its presence there is inversely proportional to the amount of analyte in the sample exactly as claimed. Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The arguments with respect to the 103 rejection of the claims over Clemmons are not persuasive. Clemmons teaches the claimed invention as described above. Clemmons does not specifically state that a kit comprising the test strips, however, the kit of the instant invention is

nothing more than the test strips themselves, and since Clemmons anticipates the test strips, Clemmons is seen to disclose the invention as claimed.

The argument that Reinke does not teach the two strips of claim 16 and therefore, the claims are not obvious over Clemmons in view of Reinke is not persuasive. Contrary to Applicant's assertion, Clemmons does not teach away from the invention, instead, Clemmons discloses each and every element of the kit of claim 16. Clemmons, however, does not teach that its device can detect thromboxane B2. Reinke is cited for its disclosure of the importance of detecting thromboxane B2 and teaches assays for their detection. Reinke discloses thromboxane B2-BSA conjugates, monoclonal antibodies specific to thromboxane B2 and three different types of enzymes detection system. Therefore, a skilled artisan would have had a reasonable expectation of success in modifying the device of Clemmons to detect thromboxane B2 using the reagents taught by Reinke because Clemmons teaches that their device is suitable for a variety of analytes with the choice of appropriate reagents and Reinke teaches that the measurement of thromboxane is important because an increase in biosynthesis of thromboxane is observed in patients with coronary diseases as well as a hosts of other problems.

The argument with respect to Guire is not persuasive. As stated above, Clemmons teaches the two strips as claimed. Clemmons differs in failing to teach the use of dyes as labels. Guire, however, discloses both enzymes and leuco dyes as labels in an immunoassay.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the enzyme label taught by Clemmons and Reinke with the leuco dyes taught by Guire because they are functionally equivalent. One having ordinary skill in the art would have been motivated to make such a change as mere alternative and functionally

equivalent labeling technique since only the expected labeling effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
December 18, 2008